

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

LABORATORY SKIN CARE, INC. :
and ZAHRA MANSOURI, :
 :
Plaintiffs, :
 :
v. : Civil Action No. 06-601-JJF
 :
LIMITED BRANDS, INC. :
and BATH AND BODY WORKS, LLC, :
 :
Defendants. :
 :

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MEMORANDUM OPINION

October 14, 2009
Wilmington, Delaware.


Farnan, District Judge

Pending before the Court are Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 102(b) (D.I. 125), Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 102 (D.I. 128), Defendants' Motion For Leave to Supplement Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 102 (D.I. 152), and the Cross Motion Of Plaintiffs' Laboratory Skin Care, Inc. And Zahra Mansouri To Preclude Defendants From Relying On The 1980 PDR Reference (D.I. 170). For the reasons discussed, the Court will deny Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 102, grant Defendants Motion For Leave To Supplement, and grant Plaintiffs' Motion to Preclude. As to Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 102(b), which seeks a judgment that the patent-in-suit is invalid pursuant to the on-sale bar of 35 U.S.C. § 102(b), pursuant to the Court's patent case Summary Judgment Procedure Order, the Court orders the parties to submit full briefing.

BACKGROUND

This is a patent infringement case brought by Plaintiffs, Laboratory Skin Care, LLC and Zahra Mansouri against Defendants, Limited Brands, Inc. and Bath and Body Works, LLC, alleging infringement of United States Patent No. 6,579,516 ("the '516 patent"), which pertains to formulations for cleansing and moisturizing the skin. Although Plaintiffs filed the

application that resulted in the '516 patent on November 28, 2000, the '516 patent traces its priority to a related June 13, 1995 application. ('516 patent at 1:5-15.)

Plaintiffs filed their Complaint (D.I. 1) on September 26, 2006, alleging infringement of Claims 2, 4-7, 13, and 15-18, all of which are dependent claims of the '516 patent. ('516 patent 14:1-68, 15:1-32, 16:1-23.) Defendants filed their Answer with Counterclaim (D.I. 10) on October 19, 2006. On December 5, 2006, the Court issued a Scheduling Order (D.I. 21) calling for the parties to file amendments to pleadings by June 28, 2007, and for discovery to end on October 5, 2007. The Court subsequently amended the Scheduling Order (see D.I. 57) to extend the deadline for document discovery to June 11, 2008, and depositions to August 11, 2008, with dispositive Motions due on September 10, 2008. Neither party filed amendments to their pleadings, and on September 10, 2008, Defendants filed two Motions For Summary Judgment Of Invalidity, one alleging that the '516 patent is invalid as anticipated (D.I. 128) and one alleging that it is invalid under the on-sale bar of 35 U.S.C. § 102(b) (D.I. 125).

Subsequently, on September 25, 2008, Defendants filed a Motion To Supplement (D.I. 152) their Motion For Summary Judgment that the '516 patent is anticipated with documents they had obtained through a third-party subpoena and that pertained to the prior art Solarcaine® product. On October 14, 2008, with their

Opposition to the Motion To Supplement, Plaintiffs filed a Cross Motion To Preclude Defendants From Relying On The 1980 PDR Reference (D.I. 170), a document that makes reference to the prior art Solarcaine® product. The parties have completed briefing on these Motions, and they are now ready for the Court's review.

DISCUSSION

I. DEFENDANTS' MOTION TO SUPPLEMENT (D.I. 152) AND PLAINTIFFS' MOTION TO PRECLUDE (D.I. 170)

A. Legal Standard

Although Defendants' Motion To Supplement their summary judgment Motion is not formally styled as a motion to supplement discovery, this is effectively what it is. Likewise, Plaintiffs' Motion To Preclude raises the question of whether supplementation of discovery should be allowed. Accordingly, the Court will apply the same legal standard to both Motions.

The supplementation of discovery is governed by Rule 26(e)(1), which states in pertinent part that "[a] party . . . must supplement or correct its disclosure or response . . . in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect" Fed. R. Civ. P. 26(e)(1). Courts consider four factors in determining whether a party has breached its duty to amend a discovery response under Rule 26(e)(1): (1) whether there was a prior response, (2) whether the response became materially

incorrect or incomplete, (3) whether the party knew that the response was incomplete, and (4) whether the corrective information was otherwise made known to the other party through the discovery process or in writing. Tritek Tech., Inc. v. United States, 63 Fed. Cl. 740, 746-47 (Ct. Cl. 2005). In cases similar to this case, the Court's focus under these factors has been whether a party has provided adequate notice of its legal contentions and their corresponding evidentiary bases. See Boehringer Ingelheim International GMBH v. Barr Laboratories Inc., No. 05-700, 2008 U.S. Dist. LEXIS 53475, at *5-*6 (D. Del. Jul. 15, 2008) (overruling plaintiff's objections to defendant's reliance on a double patenting theory because defendants submitted multiple pieces of evidence that put plaintiffs on notice).

Breaches of duty to supplement pursuant to Rule 26(e) are addressed by Rule 37(c)(1) which provides, in pertinent part: "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information . . . unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). In determining whether a failure to disclose is harmless, courts consider such factors as: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the

trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "Pennypack factors"). See Konstantopoulos v. Westvaco Corp., 112 F.3d 710, 719 (3d Cir. 1997) (citing Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 904-905 (3d Cir. 1977)).

B. Decision: Defendant's Motion To Supplement (D.I. 152)

Defendants' move to supplement their Motion For Summary Judgment that the '516 patent is invalid as anticipated with formulation sheets for the Solarcaine® product that they recently acquired through a third-party subpoena to the Schering-Plough Corporation. The Court understands Defendants' Motion as a request to rely on the Solarcaine® product itself as prior art. Opposing this Motion, Plaintiffs contend they will be unfairly prejudiced if Defendants are allowed to supplement their Motion For Summary Judgment. In particular, Plaintiffs contend that they will be forced to conduct additional discovery regarding the Solarcaine® product, including additional depositions of witnesses from Schering-Plough regarding the formulation sheets. (D.I. 169 at 3.) Moreover, Plaintiffs contend they will need to file an additional counter-statement of facts to address whether Solarcaine® constitutes anticipatory prior art. (Id.) In addition to these prejudice arguments, Plaintiffs contend that to the extent there was undue delay in acquiring and producing

documents pertaining to Solarcaine®, such delay is entirely of Defendants' own making. Specifically, Plaintiffs note that Defendants failed to subpoena third party Schering-Plough until four days before the close of discovery and that, in these circumstances, the Court should not allow Defendants to, in effect, force a modification of the dates for discovery and dispositive motions. (Id. at 4-5.)

Though finding this to be a close question, the Court will grant Defendants' Motion To Supplement. The Court first notes that, as a practical matter, Defendants' filing and serving of their subpoena, which requested documents that referenced the Solarcaine® product, notified Plaintiffs in advance of the discovery deadline that Defendants may rely on the Solarcaine® product as prior art. (See D.I. 169, Exh. A at 5.) As to whether Defendants were nonetheless tardy in pursuing their subpoena, Defendants state that they attempted to obtain relevant documents from Schering-Plough through less intrusive means, and only resorted to a formal subpoena when it became apparent that informal means of acquiring documents would not bear fruit. (D.I. 183 at 2.) Given the sometimes delicate and touchy process of acquiring documents from third parties, the Court is sympathetic to this explanation. Indeed, Defendants' decision to nevertheless pursue a formal subpoena (see D.I. 169, Exh. A) in advance of the August 10, 2008 discovery deadline reflects

diligence on the part of Defendants. Furthermore, on September 25, 2008, after Defendants received documents from Schering-Plough, Defendants both filed their Motion For Leave To Supplement and served a supplemental response to Plaintiffs' Interrogatory No. 11, which requested information regarding Defendants' invalidity contentions.¹ (D.I. 169, Exh. G.) The Court finds this relatively short time frame - only about seven weeks - for requesting third-party documents and then formally supplementing discovery constitutes further evidence of diligence on the part of Defendants. In these circumstances, the Court cannot find that Defendants breached their duty to supplement discovery and that, to the extent they did, the breach was justified.

Finally, to the extent Plaintiffs contend they will be prejudiced by the Court granting Defendants' Motion, the Court will grant Plaintiffs limited discovery regarding the Schering-

¹ Plaintiffs' Interrogatory No. 11 is as follows:

Explain in detail the complete factual basis for your contention that the '516 patent is invalid, including a detailed explanation of each legal theory upon which you base any invalidity contentions, identifying with particularity each event, disclosure, reference, or publication forming the basis for such contention, including each party or person with knowledge of any such event, disclosure, reference, publication and all documents and things that support, contradict or relate to your contention.

(D.I. 169, Exh. B at 7.)

Plough documents. Specifically, the Court will allow Plaintiffs to seek one deposition from Schering-Plough and, following the deposition, pursue limited follow-up document discovery from Schering-Plough. The Court will further grant Plaintiffs leave to file additional summary judgment papers pertaining to the Solarcaine® product following such discovery.

C. Decision: Plaintiffs' Motion To Preclude (D.I. 170)

Plaintiffs move to preclude Defendants from relying on the 1980 Physician's Desk Reference ("PDR") as prior art. Briefly, the PDR is a publicly available compilation of manufacturers' information on prescription and over-the-counter medical products that includes an entry on the Solarcaine® product. Plaintiffs contend that they did not receive fair notice of the 1980 PDR because Defendants never specifically mentioned it in their response to Plaintiffs' Interrogatory No. 11. At most, Plaintiffs contend that Defendants referred indirectly to the 1990 PDR in their interrogatory responses by generally calling out a Bates range of documents of over 1,500 pages that happened to encompass the relevant three-page portion of the PDR. Plaintiffs contend that they had no way of knowing which reference within these 1,500 pages, if any, Defendants believed anticipated the '516 patent. Plaintiffs further contend that even if a reference to 1,500 pages of documents could be regarded as an adequate disclosure of the 1990 PDR, Defendants never

disclosed - in any way - the 1980 PDR that they actually relied upon in their Motion For Summary Judgment.² Defendants respond essentially that they produced the 1990 PDR on the final day of document production and that, in so doing, they put Plaintiffs on specific notice of the PDR well in advance of their Motion For Summary Judgment. (See D.I. 189 at 2-3.)

The Court finds that Defendants did not adequately put Plaintiff on notice of the PDR prior to filing their Motion For Summary Judgment. To the extent Defendants disclosed the 1990 PDR in a supplemental interrogatory response in advance of the discovery deadline, the disclosure was buried within roughly 1,500 pages of documents that were otherwise identified only by broad ranges of Bates numbers. (See D.I. 169, Exh. E at 7.) Defendants cannot reasonably expect Plaintiffs to be on notice of a three page reference - buried within roughly 1,500 pages of numerically identified documents - that was neither called out by specific Bates number nor by name. Such identification, or lack thereof, does not qualify as adequate notice of Defendants' invalidity contentions. Accordingly, the Court finds that the Defendants breached their duty to supplement under Rule 26(e).

² The parties contest whether the reference to Solarcaine® in 1990 and 1980 PDRs are identical. However, neither party has provided a copy of the 1990 PDR. Accordingly, the Court will not speculate as to this point, but will assume for the purpose of ruling on this motion that the two PDRs are identical so as to focus on the more pertinent issue of whether Plaintiffs had notice of any PDR, regardless of issue date.

The Court further finds that Defendants failure to disclose was neither justified nor harmless. Indeed, Plaintiffs' first notice of the fact that the PDR constituted possible prior art was Defendants' Motion For Summary Judgment. Defendants have not, in the Court's view, provided any evidence or given any explanation as to why they failed to identify the PDR as anticipatory prior art to the '516 patent. Accordingly, the Court will preclude Defendants from further relying on either the 1980 or 1990 version of the PDR with respect to their anticipation defenses.

II. DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT

A. Legal Standard

In pertinent part, Rule 56(c) of the Federal Rules of Civil Procedure provides that a party is entitled to summary judgment if a court determines from its examination of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any," that there are no genuine issues of material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). In determining whether there is a triable dispute of material fact, a court must review all of the evidence and construe all inferences in the light most favorable to the non-moving party. Valhal Corp. v. Sullivan Assocs., Inc., 44 F.3d 195, 200 (3d Cir. 1995).

To defeat a motion for summary judgment, the non-moving party must "do more than simply show that there is some metaphysical doubt as to the material facts. . . . In the language of the Rule, the non-moving party must come forward with specific facts showing that there is a genuine issue for trial." Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986) (internal citations omitted). However, the mere existence of some evidence in support of the non-movant will not be sufficient to support a denial of a motion for summary judgment; there must be enough evidence to enable a jury to reasonably find for the non-movant on that issue. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986). Thus, if the evidence is "merely colorable, or is not significantly probative," summary judgment may be granted. Id.

B. Summary Judgment Under 35 U.S.C. § 102: Anticipation

1. Applicable Legal Principles

In the context of summary judgment, anticipation is generally a question of fact. Upsher-Smith Labs., Inc. v. PamLab, LLC, 412 F.3d 1319, 1322 (Fed. Cir. 2005) (citation omitted). Nevertheless, summary judgment can be appropriate for anticipation if there are no genuine issues of material fact. Gen. Elec. Co. v. Nintendo Co., 179 F.3d 1350, 1353 (Fed. Cir. 1999).

An invention is anticipated under 35 U.S.C. § 102(b) if it "was . . . described in a printed publication in this . . . country . . . more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2002). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." In re Paulsen, 30 F.3d 1475, 1478-79 (Fed.Cir.1994) (citing In re Spada, 911 F.2d 705, 708 (Fed. Cir. 1990)); see also Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1576 (Fed. Cir. 1991) ("There must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention."). Such disclosure can be explicit or inherent in the prior art. In re Schrieber, 128 F.3d 1473, 1477 (Fed. Cir. 1997). However, mere disclosure of each and every limitation of a claim is not enough for anticipation. Indeed, "[a]n anticipating reference must enable that which it is asserted to anticipate." Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1345 (Fed. Cir. 2008). Furthermore, a single prior art reference must also disclose the limitations as arranged in the claim. Net Moneyin, Inc. v. Verisign, Inc., 545 F.3d 1359, 1371 (2008) (internal citations omitted). The requirement for the prior art to be arranged as in the claim bespeaks the notion that "the hallmark of anticipation is prior invention." Id. at 1369.

2. Decision

Defendants contend that five prior art references invalidate some or all of the asserted claims. All of the asserted claims depend from either independent Claim 1 or Claim 12. Independent Claim 1 of the '516 patent is as follows:

1. A moisturizing composition for applying to and leaving on human skin, the composition in the form of an antimicrobial lotion composition comprising:
 - (a) an amount of triclosan effective to kill microorganisms present on the skin;
 - (b) an emollient present in an amount effective to moisturize the skin; and
 - (c) a lotion base comprised of a physiologically and cosmeceutically acceptable vehiclewherein said components of said lotion are present in amounts sufficient to provide an effective antimicrobial lotion.

('516 patent 14:9-21.) Independent Claim 12 of the '516 patent presents limitations similar to those of Claim 1, but rather than being a composition claim, is a method claim directed to a "method for moisturizing the skin and killing microorganisms thereon." (*Id.* at 15:16-29.) The parties disputed many terms in these claims. However, only two terms required additional construction by the Court. First, the Court construed "physiologically and cosmeceutically acceptable vehicle" to mean "a solvent, diluent, or dispersant for the constituents of the composition that allows for the uniform application of the constituents to the surface of the skin at an appropriate dilution." (D.I. 194 at 23-26.) Second, the Court construed the

terms "effective antimicrobial lotion," "antimicrobial lotion" and "antimicrobial lotion composition" all to mean "a lotion that effectively inhibits the growth of or kills microorganisms present on the skin." (Id. at 26-27.) With these constructions in mind, the Court now turns to each prior art reference.

a. The Boothe Patent

Defendants contend that United States Patent No. 4,764,365 issued to Boothe et al. ("Boothe") on August 16, 1988 anticipates Claims 1-5 and 12-16 of the '516 patent. (D.I. 129 at 13.) Claims 1 and 12 of the '516 patent, from which the asserted claims depend, require the antimicrobial lotion to comprise an emollient, an amount of triclosan effective to kill microorganisms present on the skin, and a lotion base comprised of a physiologically and cosmeceutically acceptable vehicle. ('516 patent at 14:9-21.) As to the lotion requirement, the Boothe patent discloses "personal skin care products" that can be used for, inter alia, "hand and face lotions." (Boothe at 2:55-59.) As to the "cosmeceutically acceptable vehicle" element of the claims, the Boothe patent discloses that the "personal skin care products" can comprise, "other cosmetically acceptable excipients," and provides examples within three categories of excipients. (Id. at 3:13-36 (emphasis added).) The Boothe patent further states that personal skin care products, such as lotions, "generally comprise an active agent, such as a detergent

or surfactant, conditioner, emollient, antimicrobial, antiperspirant and moisturizing agent." (Id. at 2:64-67 (emphasis added).) With further regard to the "emollient" element of the claims, Boothe further discloses the use of a range of specific emollients. (Id. at 3:8-12.) With regard to the antimicrobial component, although Boothe specifically discloses the use of triclosan, (id. at 2:68-3:4), it does not disclose the killing of microorganisms on the skin, as the claims require. Indeed, Boothe mentions triclosan only once, providing no recommended concentration and/or any indication as to whether it should be employed to kill microorganisms on the skin or, alternatively, as a mere preservative. Having reviewed Defendants Opening Brief in support of its Motion For Summary Judgment, the Court further concludes that Defendants have not presented any meaningful evidence to establish that the killing of microorganisms on the skin would be inherent in Boothe's cursory reference to triclosan. Accordingly, although Boothe may come close to being an anticipatory reference upon which summary judgment may be granted, the Court nevertheless concludes that summary judgment on the issue of whether Boothe anticipates the asserted claims is not warranted.

b. The Honda Patent

Defendants contend that United States Patent No. 5,112,613 issued to Honda et al. ("Honda") on May 12, 1992 anticipates

claims 1-7 and 12-18 of the '516 patent. Honda pertains to a "cosmetic composition comprising N-acetyleglutamine or salt thereof which is free from drawbacks involved in cosmetic bases theretofore used and is effective to enhance moisture retention in the stratum corneum." (Honda at 1:50-57.) Though Honda describes the use of emollients and other "cosmetically acceptable components," the Court finds that there is a factual dispute as to whether Honda teaches the use of "an amount of triclosan effective to kill microorganisms present on the skin," as recited in Claim 1 of the '516 patent. To the extent Honda teaches the use of triclosan, it does so not for the purpose of killing microorganisms on the skin, but as a preservative system for the product. (Id. at 2:68-3:1.) Indeed, unlike Boothe, Honda does not even refer to triclosan as an "antimicrobial" component. In fact, on reviewing Honda, the Court finds no reference to the inhibition of the growth of microorganisms on the skin or the killing of microorganisms on the skin.

Defendants note that Honda teaches the use of triclosan in the range of 0.01 to 0.3%, (Honda at 3:1-3), and that this range overlaps with preferred ranges of triclosan in the '516 patent. (See '516 patent at 4:42-45 ("The antimicrobial component is normally present in an amount of from 0.001-5% by weight, preferably from 0.05-2% by weight, and more preferable from 0.1-1% by weight.")) Based on this, Defendants contend that Honda

discloses an amount of triclosan effective to kill microorganisms on the skin. In other words, Defendants appear to contend that the killing of microorganisms is inherent in Honda. However, in the Court's view, Defendants have not provided any evidence that 0.01 to 0.3% triclosan, when used in conjunction with the formulations set forth in Honda, would, in fact, be effective to kill microorganisms on the skin, as the claims of the '516 patent require. This point is critical because the asserted claims of the '516 patent include distinct limitations directed to (1) an amount of triclosan effective to kill microorganisms on the skin, and (2) specific concentrations of triclosan. In these circumstances, the Court cannot, as Defendants request, conflate a particular concentration of triclosan with an amount of triclosan effective to kill microorganisms on the skin. Indeed, while the former is static, the latter may conceivably vary as a function of the other components present in the composition. Because all of the asserted claims require, through dependency, an amount of triclosan effective to kill microorganisms on the skin, the Court finds that summary judgment is inappropriate as to whether Honda anticipates the claims of the '516 patent.

c. The Elliott Patent

Defendants contend that United States Patent No. 4,954,532 issued to Elliott et al. ("Elliott") on January 30, 1985 anticipates claims 1-5 and 12-16 of the '516 patent. Elliott

describes the use of a silanised adsorbents in antiseborrheic compositions. (Elliott at 1:4-6.) As Plaintiffs note, unlike Boothe, Elliot does not disclose the use of an antimicrobial within an integrated description of a cosmetic product, such as a lotion. Rather, Elliott merely discloses that the claimed compositions "may also comprise optional accessory ingredients such as suspending agents, perfume, colouring and preserving agents, pigments, keratoloytics, antibacterials and antimicrobial agents such as Irgasan and chlorhexidine." (Elliott at 2:34-38.) Because Elliott Discloses an antimicrobial as a mere "optional accessory ingredient" among a list of other "optional accessory ingredients," the Court agrees with Plaintiffs that there remains a genuine issue of material fact as to whether an undue level of hindsight would be required to rearrange the disclosure of Elliott to arrive at the moisturizing compositions claimed in the '516 patent. Accordingly, the Court concludes that summary judgment is not appropriate on the issue of anticipation by Elliott.

d. The Schindlery Patent

Defendants contend that United States Patent No. 4,512,987 issued to Schindlery ("Schindlery") on April 23, 1985 anticipates claims 1-7 and 12-18 of the '516 patent. The Schindlery patent concerns the invention of new pharmaceutical preparations for topical administration for the treatment of eczematous dermatoses

or other forms of inflamed dermatoycoses and pyodermias. (Schindlery at 1:4-9.) On reviewing Schindlery, the Court concludes that although it teaches creams, it does not teach moisturizing lotions, which is what the claims of the '516 patent are explicitly directed to. Accordingly, the Court concludes that summary judgment is inappropriate on the issue of whether Schindlery anticipates the '516 patent.

e. The Physician's Desk Reference

Defendants contend that the 1980 PDR anticipates the '516 patent. However, as explained above, the Court will grant Plaintiffs' Motion To Preclude this reference. Accordingly, Defendants may not rely on this reference either in this Motion For Summary Judgment or at trial.

C. Summary Judgment Under 35 U.S.C. § 102(b): On-Sale Bar

1. Applicable Legal Principles

In pertinent part, 35 U.S.C. § 102(b) states that "[a] person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of application for patent in the United States." 35 U.S.C. § 102(b) (2002). To trigger the on-sale bar under Section 102(b), the alleged infringer must prove that the product sold "fully anticipated the claimed invention or would have rendered the claimed invention obvious by its addition to the prior art." Allen Eng. Corp. v. Bartell Indus., Inc., 299 F.3d 1336, 1352

(Fed. Cir. 2002) (quoting Tec Air, Inc. v. Denso Mfg. Mich., Inc., 192 F.3d 1353, 1358 (Fed. Cir. 1999)). Therefore, an accused infringer must show that the product offered for sale "embodied all of the limitations of that claim or would have rendered that claim obvious." Allen, 299 F.3d at 1352. In addition, the accused infringer must establish by clear and convincing evidence that before the critical date the product was (1) the subject of a commercial offer for sale, and (2) that the invention was ready for patenting. See Pfaff v. Wells Elecs., 525 U.S. 55, 67 (1998). Under the first prong of Pfaff, courts should determine whether there has been a commercial offer for sale by "applying traditional contract law principles." Allen, 299 F.3d at 1352. The second prong of Pfaff "may be satisfied in at least two ways: by proof of reduction to practice before the critical date; or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." Pfaff, 525 U.S. at 67-68.

2. The Parties' Contentions

Defendants contend that Plaintiffs sold an embodiment of the '516 patent before the June 13, 1994 critical date and that the patent is thus invalid pursuant to the on-sale bar of 35 U.S.C. §

102(b).³ Specifically, Defendants contend that Plaintiffs provided manufacturer Francosmetics International, Inc. ("Francosmetics") with a moisturizer formulation sheet and processing instructions describing how to prepare a preferred embodiment of the '516 patent. (D.I. 126 at 11.) Defendants further allege that after Francosmetics manufactured such moisturizing formulations, Plaintiffs sold it to two distributors, Baxter Scientific Products ("Baxter") and Paxxis, Inc. ("Paxxis"). (Id. at 13-14.)

In response, Plaintiffs assert that the moisturizer they sold to Baxter and Paxxis was contaminated. Because of this contamination, Plaintiffs contend, the moisturizer did not contain "an amount of triclosan effective to kill microorganisms on the skin," a limitation of both Claims 1 and 12 of the '516 patent. (D.I. 160 ¶ 3.) Thus, according to Plaintiffs, the moisturizer they sold did not trigger the on-sale bar because it did not meet this limitation of Claims 1 and 12. In addition to Francosmetics's alleged inability to produce an embodiment of the moisturizer, Plaintiffs claim that two other manufactures, Libby Laboratories and Gordon Laboratories, were also unable to produce

³ Here, the priority date for the '516 patent is June 13, 1995. Accordingly, the critical date for the purposes of the on-sale bar is June 13, 1994. See 35 U.S.C. 102(b) ("[a] person shall be entitled to a patent unless . . . the invention was . . . on sale in this country, more than one year prior to the date of application for patent in the United States.") (emphasis added).

an embodiment of the moisturizer prior to June 13, 1994.⁴ (Id. at ¶ 9.) These additional episodes, Plaintiffs contend, demonstrate that they not only failed to sell an embodiment of the claimed invention, but that their invention had not actually been fully conceived at the time of the offer for sale to Baxter and Paxxis. Thus, Plaintiffs contend that there also remains a genuine issue of material fact with respect to the second prong of Pfaff.

3. Decision

The Court finds that, on the current record, full summary judgment briefing is required on the issue of whether the '516 patent is invalid under the on-sale bar of 35 U.S.C. § 102(b). Accordingly, the Court orders further briefing in accordance with a schedule to be proposed by the parties.

VI. CONCLUSION

For the foregoing reasons, the Court denies Defendants' Motion For Summary Judgment Of Invalidity Under 35 U.S.C. § 102 (D.I. 128), grants Defendants' Motion For Leave To Supplement (D.I. 152), and grants Plaintiffs' Motion to Preclude (D.I. 170). As to Defendants' Motion For Summary Judgment Of Invalidity Under

⁴ In their Reply Brief in support of their Motion For Summary Judgment, Defendants confirm that they rely only on the alleged offer to sell the products that were manufactured by Francosmetics. (D.I. 165 at 7 ("The Limited Defendants' Opening Brief does not even mention - much less rely on - any facts surrounding the work performed by Libby or Gordon.").)

35 U.S.C. § 102(b) (D.I. 125), the Court requests complete briefing to be completed in accordance with a schedule agreed upon by the parties.

An appropriate Order will be entered.